**EMM**

Exact Medical Manufacturing, Inc.

OCT 4 2010

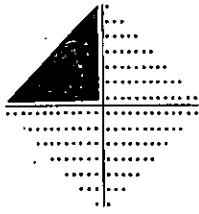
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K101598

Sec. 6: 510(k) Summary – EMM Surgical Drape SMS w/PE Sides

510(k) Summary for Exact Medical Manufacturing Inc., EMM Surgical Drape – SMS w/PE Sides

Date Summary was Prepared	July 29, 2010 (rev.1)
510(k) Submitter	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p) 716-681-0866, (f) 716-681-4110
Primary Contact for this 510(k) Submission	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street Lancaster, NY 14086 dnowicki@exactmm.com (p) 716-681-0866, (f) 716-681-4110
Device Common Name	Surgical Drape
Trade Name	EMM Surgical Drape SMS w/PE Sides, Model 13-005
Device Product Codes and Classification Name	KKX, 21CFR878.4370, Surgical Drape and Drape accessories, Class II
Predicate Device	Primeline (Primagard) Surgical drapes 510(k)021864
Device Description	<p>Exact Medical Manufacturing Surgical Drapes Surgical Drape SMS w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.</p> <p>Exact Medical Manufacturing Surgical Drapes SMS w/PE Sides are comprised of a single layer of SMS (spunbond/meltblown/spunbond polypropylene), PE Layer, 3M Medical Adhesive Tape.</p>
Intended Use	<p>Exact Medical Manufacturing Surgical Drape Surgical Drape SMS w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.</p> <p>The Exact Medical Manufacturing Surgical Drape Surgical Drape SMS w/PE Sides are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization</p>
Technological Characteristics	Exact Medical Manufacturing Surgical Drape Surgical Drape SMS w/PE Sides has the same design, material and performance characteristics of the predicate device. Additional summary and explanation of technological characteristics is included in the following Addendum A.
Summary of Testing	Exact Medical Manufacturing Surgical Drape Surgical Drape SMS w/PE Sides is substantially equivalent and meets the same acceptance criteria as the predicate device/gown in K021864. Non-clinical performance testing includes: Biocompatibility (cytotoxicity, irritation, sensitization) in compliance with the methods of ISO 10993, Barrier properties AAMI PB-70 Level 3, tensile, tear strength, flammability, linting and sterility. All results of the testing met acceptance criteria. Additional summary and explanation of non-clinical testing is included in the following Addendum B.
Substantial Equivalence	The surgical drapes described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device identified in K021864 except for minor variations in the widths and lengths.

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Addendum A.**Summary and Explanation of Technological Characteristics:****EMM SURGICAL DRAPE SMS w/PE Sides Predicate Device Comparison Table**

Exact Medical Manufacturing - Surgical Drape SMS w/PE Sides Model # 13-005	Substantially Equivalent	Primeline (Primagard) Surgical Drapes 510(k)021864 PREDICATE DEVICE
Indications for Use: Exact Medical Manufacturing Surgical Drape SMS w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.	Substantially Equivalent	devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.
Classification & Code: KXX, Surgical Drapes, 21CFR878.4370, Class II	Substantially Equivalent	Classification & Code: KXX, Surgical Drapes, 21CFR878.4370, Class II
Materials & Construction: SMS (spunbond/meltblown/spunbond polypropylene), Polyethylene, Absorbent Reinforcement, 3M medical grade adhesive	Substantially Equivalent	SMS, absorbent reinforcement, 3M medical grade adhesive
Barrier properties AATCC 42:2007, AATCC 127:2008: Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for Use in Health Care Facilities, AAMI PB70:2003 (R)2009, Level 3. Hydrostatic Head ≥ 50 cm	Substantially Equivalent	Hydrostatic head = 30.5 cm
Sterile (via EO Gas) ISO 11135-1:2007, Sterilization of health care products - Ethylene Oxide - Part 1	Not Applicable	Non-sterile
Non-Sterile	Substantially Equivalent	Non-sterile
Sterile Packaging: Chevron peel pouch (coated paper (73gsm), PET12/PE40 film construction), individual CSR internal wrap	Not Applicable	Not Applicable
Biocompatibility: cytotoxicity, irritation and sensitization - ISO 10993-5:1999, Cytotoxicity , ISO 10993-10:2002, Skin Irritation , ISO 10993-10:2002, Sensitization . Cytotoxicity, Irritation, Sensitization tests PASS	Substantially Equivalent	Cytotoxicity, Irritation, Sensitization PASS
Tear Strength - ASTM D5587-08 (no rev.) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure. Tensile Strength for Md and Cd within general industry tolerance +/- 20%	Substantially Equivalent	Md=1.83 lbs Cd= 3.24 lbs
Tensile Strength - ASTM D5034-09 (no rev.) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) Tensile Strength for Md and Cd within general industry tolerance +/- 20%	Substantially Equivalent	Md=13.8 lbs Cd=18.8 lbs
Flammability - 16CFR1610:2010, Flammability of Clothing Textiles Class 1 - PASS	Substantially Equivalent	Class 1
Lint and other Particles generated in the dry state - ISO 9073-10:2003	Not Applicable	No test



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Exact Medical Manufacturing, Incorporated
C/O Mr. Robert O. Dean
Compliance Systems International, LLC
1083 Delaware Avenue
Buffalo, New York 14209

OCT 4 2010

Re: K101598

Trade/Device Name: Exact Medical Manufacturing Surgical Drape SMS w/PE
Sides, Model 13-005
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKK
Dated: September 17, 2010
Received: September 24, 2010

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2- Mr. Dean

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Watson" followed by a stylized flourish.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use:

510(k) Number (if known): K101598

Device Name: Exact Medical Manufacturing Surgical Drape SMS w/PE Sides, Model 13-005

Indications for Use: Exact Medical Manufacturing Surgical Drape SMS w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

The Exact Medical Manufacturing Surgical Drape SMS w/PE Sides are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Elizabeth F. Lawrence-Williams
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101598